AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A method of detecting cancer-associated ~~anti-tumour~~ anti-tumor autoantibodies in a sample, which method is an immunoassay, comprising:

contacting ~~a~~ the sample to be tested for ~~the~~ presence of ~~such~~ the anti-tumor autoantibodies with an immunoassay reagent; and

detecting ~~the~~ a presence of complexes formed by specific binding of the immunoassay reagent to any cancer-associated ~~-tumour~~ anti-tumor autoantibodies present in the sample,

wherein the immunoassay reagent comprises one or more tumor ~~tumour~~ marker protein prepared from a bodily fluid, derived from a body cavity or space in which a tumor ~~tumour~~ is or was present or with which ~~a tumour~~ is or was associated, of one or more cancer patients ~~and/or~~ or a tumor ~~tumour~~ marker protein prepared from an excretion of one or more cancer patients,

wherein said one or more tumor ~~tumour~~ marker protein exhibits selective reactivity with cancer-associated ~~anti-tumour~~ anti-tumor autoantibodies.

2. (Currently Amended) A method according to claim 1, which comprises ~~performing an immunoassay to detect and/or quantitatively measure~~ one or more of detecting or quantitatively measuring a ~~the~~ presence of two or more types of autoantibodies,

wherein each one of the two or more types of the autoantibodies is immunologically specific to a different ~~tumour~~ tumor marker ~~proteins~~ protein or to ~~two or more~~ a ~~different epitope~~ epitopes of ~~the~~ same ~~tumour~~ tumor marker protein,

wherein the immunoassay is carried out using a panel of two or more immunoassay reagents, at least one of ~~which reagents comprises~~ of the two or more immunoassay reagents comprising ~~a tumour~~ the one or more tumor marker protein prepared from the bodily fluid derived from ~~a~~ the body cavity or space from the one or more cancer patients ~~and/or tumour~~ or the tumor marker protein prepared from ~~an~~ the excretion from the one or more cancer patients.

3. (Currently Amended) ~~Use of the~~ The method of claim 1 or claim 2 ~~for the detection or diagnosis of cancer in a patient~~, wherein the sample ~~to be tested using the immunoassay~~ is a sample of a bodily fluid from taken from ~~the~~ a patient in need of detection or diagnosis of cancer, and wherein ~~the~~ a presence of an elevated level of the anti-tumor autoantibodies in the sample, as compared to a normal control ~~individuals~~, is taken as an indication that the ~~individual~~ patient in need of detection or diagnosis of cancer has or is developing a cancer.

4. (Currently Amended) ~~Use of the~~ The method of claim 1 or claim 2 ~~in monitoring the progress of cancer or other neoplastic disease in a patient~~, wherein the sample ~~to be tested~~ using the immunoassay is a sample of a bodily fluid taken from ~~the~~ a patient in need of monitoring of progress of cancer or other neoplastic disease, and wherein ~~the~~ a presence of an elevated level of the anti-tumor autoantibodies in the sample, as compared to a normal control, is taken as an indication of ~~the~~ presence of a cancer in the patient in need of monitoring of progress of cancer or other neoplastic disease.

5. (Currently Amended) ~~Use of the~~ The method of claim 1 or claim 2 ~~in detecting early neoplastic or early carcinogenic change in an asymptomatic subject~~,

wherein the sample ~~to be tested using the immunoassay~~ is a sample of bodily fluid taken from ~~the~~ an asymptomatic subject, and wherein ~~the~~ a presence of an elevated level of the anti-tumor autoantibodies in the sample, as compared to a normal control ~~individuals~~, is taken as an indication of early neoplastic or early carcinogenic change in the asymptomatic subject.

6. (Currently Amended) ~~Use of the~~ The method of claim 1 or claim 2 ~~in screening a population of asymptomatic human subjects to identify those subjects who are at increased risk of developing cancer~~, wherein the sample ~~samples to be tested using the immunoassay are samples~~ is a sample of a bodily fluid taken from an asymptomatic human subject selected from a population of asymptomatic human subjects in need of a screening for a risk of developing cancer ~~the subjects~~, and wherein ~~subjects having~~ a presence of an elevated level of the anti-tumor autoantibodies in the sample, as compared to a normal control ~~individuals, are identified~~ identifies the subject as being at risk of developing cancer.

7. (Currently Amended) ~~Use of the~~ The method of claim 1 or claim 2 ~~in monitoring the response of a cancer patient to anti- cancer treatment~~, wherein the sample ~~to be tested using the immunoassay~~ is a sample of bodily fluid taken from ~~the~~ a cancer patient in need of monitoring a response of the cancer patient to an anti-cancer treatment, and wherein the presence of a decreased level of the anti-tumor autoantibodies in a sample after the anti-cancer treatment as compared to the level of the anti-tumor autoantibodies in a sample before the anti-cancer treatment is taken as an indication that the patient has responded positively to the treatment.

8. (Currently Amended) ~~Use of the~~ The method of claim 1 or claim 2 ~~in the detection of recurrent disease in a patient previously diagnosed as having cancer, which patient has undergone anti-cancer treatment to reduce the amount of cancer present~~, wherein the sample ~~to be tested using the immunoassay~~ is a sample of bodily fluid taken from ~~the~~ a patient in need of detection of a recurrent disease, wherein the patient was

previously diagnosed as having cancer and undergone anti-cancer treatment to reduce amount of cancer, and wherein ~~the~~ presence of an increased level of autoantibodies in the patient, as compared to a normal control, is taken as an indication that the disease has recurred.

9. (Currently Amended) ~~Use of the~~ The method of claim 2 ~~in the selection of an anti-cancer vaccine for use in a particular patient~~, wherein the immunoassay is carried out using a panel of two or more immunoassay reagents, wherein each one of the two or more immunoassay reagents is for detection of ~~corresponding to~~ a different ~~tumour~~ tumor marker protein, wherein the sample is obtained from a patient, the method further comprising:

determining ~~in order to determine~~ ~~the~~ relative strength of ~~the patient's~~ immune response of the patient to each one of the two or more different ~~tumour~~ tumor marker proteins[[,]]; and

~~wherein the tumour marker protein or proteins identified as eliciting the strongest immune response or responses in the patient is or are selected~~ selecting one or more tumor marker proteins to form ~~the~~ a basis of an anti-cancer vaccine for use in said patient, wherein the one or more tumor marker proteins to which the patient has strongest immune response is selected out of the two or more different tumor marker proteins.

10. (Currently Amended) A method of determining whether a vaccination procedure, comprising challenging a patient with an immunogenic preparation comprising a ~~tumour~~ tumor marker protein or an antigenic fragment thereof or with a nucleic acid sequence expressing said ~~tumour~~ tumor marker protein, has been successful in eliciting cancer-associated antibodies to the ~~tumour~~ tumor marker protein in the patient, ~~which~~ wherein the method is an immunoassay, comprising:

contacting a sample of bodily fluid from the patient with an immunoassay reagent; and

detecting ~~the~~ presence of complexes formed by specific binding of the immunoassay reagent to any cancer-associated antibodies present in the sample,

wherein the immunoassay reagent comprises a sample of the ~~said tumour~~ tumor marker protein,

wherein the tumor marker protein is prepared from a bodily fluid derived from one or more of a body cavity or in which a ~~tumour~~ tumor is or was present or with which a tumour is or was associated ~~from~~ of one or more cancer patients, ~~and/or~~ or ~~tumour marker protein prepared~~ from an excretion from one or more cancer patients, wherein said ~~tumour~~ tumor marker protein exhibits selective reactivity with cancer-associated ~~anti-tumour~~ anti-tumor antibodies.

11. (Currently Amended) [[A]] The method according to any one of claims 1, 2 or 10, wherein the bodily fluid derived from ~~a~~ the body cavity or space is ascites fluid, pleural effusion, seroma, hydrocoele or wound drainage fluid.

12. (Currently Amended) The ~~use~~ method according to ~~anyone of claims 3 to 9~~ claim 3, wherein the bodily fluid derived from a body cavity or space is ascites fluid, pleural effusion, seroma, hydrocoele or wound drainage fluid.

13. (Currently Amended) [A]] The method according to any one of claims 1, 2 or 10, wherein the excretion is urine, faeces or seminal fluid.

14. (Currently Amended) The ~~use~~ method according to ~~any one of claims 3 to 9~~ claim 3, wherein the excretion is urine, faeces or seminal fluid.

15. (Currently Amended) [[A]] The method according to claim 11 ~~or 13~~, wherein the ~~tumour~~ tumor marker protein is selected from MUC1, MUC16 or c-myc.

16. (Currently Amended) The ~~use~~ method according to claim 12 ~~or 14~~, wherein the ~~tumour~~ tumor marker protein is selected from MUC1, MUC16 or c-myc.

17. (Currently Amended) [[A]] The method according to any one of claims 1, 2, or 10, ~~11 or 13~~ wherein the ~~tumour~~ tumor marker protein is selected from c-erbB2, p53, ras, BRCA1, BRCA2, APC, PSA, CEA, and CA19.9.

18. (Currently Amended) The ~~use~~ method according to claim 3 ~~any one of claims 3 to 9, 12 or 14~~, wherein the ~~tumour~~ tumor marker protein is selected from c-erbB2, p53, ras, BRCA1, BRCA2, APC, PSA, CEA and CA19.9.

19. (Original) Use of tumour marker protein prepared from bodily fluid derived from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated, of one or more cancer patients and/or tumour marker protein derived from an excretion of one or more cancer patients in the manufacture of an immunoassay reagent exhibiting selective reactivity with cancer-associated anti- tumour autoantibodies.

20. (Original) A method of preparing a tumour marker protein which method comprises isolating said tumour marker protein from bodily fluid wherein said fluid is : (i) collected from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated, and (ii) said fluid represents the pooled fluid samples from two or more cancer patients.

21. (Original) A method as claimed in claim 20 wherein said fluid is acites, pleural effusion, seroma, hydrocoele or wound drainage fluid or a mixture thereof.

22. (Original) A method as claimed in claim 21 wherein said tumour marker protein is MUC1.

23. (Original) A method as claimed in claim 20 or 21 wherein said tumour marker protein is c-erbB2, p53, ras, BRCA1, BRCA2, APC, PSA, CEA, CA19. 9, MUC16 or c-myc.

24. (Original) A method of preparing a tumour marker protein which method comprises isolating said tumour marker protein from a bodily fluid collected from a body cavity or space in which a tumour is or was present or with which a tumour is or was associated wherein said bodily fluid is wound drainage fluid, seroma, hydrocoele or a mixture thereof.

25. (Original) A method of preparing a tumour marker protein which method comprises isolating said tumour marker protein from an excretion wherein: (i) said excretion or any component thereof has been in contact with a tumour or tumour cells, and (ii) said excretion represents pooled excretion samples from two or more cancer patients.

26. (Original) A method as claimed in claim 25 wherein said excretion is urine, faeces or seminal fluid.

27. (Original) A method as claimed in claim 25 or 26 wherein the relevant component of said excretion is bile.

28. (Original) A method as claimed in any one of claims 25 to 27 wherein the tumour marker protein is MUC 1, c- erbB2, p53, ras, BRCA1, BRCA2, APC, PSA, CEA, CA19. 9, MUC16 or c-myc.

29. (Original) A method as claimed in any one of claims 20 to 28 wherein said tumour marker is purified from said fluid or excretion by affinity chromatography.

30. (Original) A method as claimed in any one of claims 20 to 29 which includes a step of removing contaminating immunoglobulin from said tumour marker protein.

31. (Original) A method as claimed in any one of claims 20 to 30 which includes a further step of immobilizing said isolated tumour marker protein to a solid support.

32. (Original) A preparation of a tumour marker protein prepared by the method of any one of claims 20 to 31 and which is substantially immunoglobulin free.

33. (Original) A kit or reagent suitable for carrying out an immunoassay which comprises a preparation of a tumour marker protein as claimed in claim 31 immobilized to a solid support.

34. (Original) A kit or reagent as claimed in claim 33 wherein said solid support is the surface of a well of a multiwell plate or is a bead.

35. (Original) A kit or reagent as claimed in claim 32 or 33 wherein said immobilized tumour marker protein is absorbed, adsorbed or covalently attached to said solid support.

36. (Original) Use of a preparation as claimed in claim 32 in the evaluation in an in vitro test for the therapeutic efficacy or safety of said tumour marker protein.

37. (Original) Use of a preparation as claimed in claim 32 in manufacture of a composition for the evaluation in an in vivo test of the therapeutic efficacy or safety of said tumour marker protein.

38. (Original) A method of calibrating an assay for measurement or detection of a given tumour marker protein in a clinical sample which method comprises the

steps of: a) preparing at least two samples of a preparation of claim 32, each of which comprises said given tumour marker protein and each of which has a different tumour marker protein concentration to each of the other said samples: b) carrying out a quantitative measurement of the concentration of said tumour marker protein in each of said samples using (i) a spectrophotometric method and/or, (ii) an antibody reagent to said tumour marker protein, and c) constructing a standard curve for a tumour marker protein concentration based on the measurements obtained in step (b).